SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 7001–7060

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its quality or purity fell below the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from or its quality fell below that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(c), a word, statement, or other information required by, or under authority of, the Act to appear on the label or labeling of the article was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; Section 502(l), the article was composed wholly or in part of a kind of penicillin, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

7001. Pre-Creatine capsules, Neo-Creatine capsules, Neo-Creatine granules, and Vi-Arthra-M capsules. (Inj. No. 419.)

COMPLAINT FOR INJUNCTION FILED: 10–13–61, N. Dist. Calif., against Andrew Doty, San Francisco, Calif.

CHARGE: The complaint alleged that the defendant was engaged in the business of promoting the interstate sale and distribution of the following drugs: *Pre-Creatine capsules, Neo-Creatine capsules, Neo-Creatine granules*, and *Vi-Arthra-M capsules;* that the *Pre-Creatine capsules, Neo-Creatine capsules*, and *Neo-Creatine granules* were offered for increasing available energy to muscles

and nerves damaged by heart and neuromuscular diseases; that the *Vi-Arthra-M capsules* were offered for energy restoration in detoxification and for the relief of pain associated with rheumatism and arthritis; that the *Pre-Creatine capsules* contained betaine anhydrous and glycocyamine; that the *Neo-Creatine capsules* and the *Neo-Creatine granules* contained betaine anhydrous and glycine; and that the *Vi-Arthra-M capsules* contained betaine, glycocyamine, glucuronolactone, para-aminobenzoic acid, sodium gentisate, and vitamin C. It was alleged further that all of these drugs were new drugs within the meaning of the law and that they may not be introduced into interstate commerce in the absence of an effective new drug application.

The complaint alleged also, with respect to the *Pre-Creatine capsules*, that the defendant submitted a new drug application in the name of Mercury Pharmaceuticals, Inc.; that, in November 1958, this new drug application became effective; and that, on November 27, 1959, this new drug application was suspended on the ground that it contained a number of untrue statements of material facts.

The complaint alleged further that, with respect to the other drugs, no new drug application was filed or ever became effective; that subsequent to November 27, 1959, the defendant continued to introduce all of these new drugs into interstate commerce without having an effective new drug application with respect to any of them; and that the defendant violated the law by causing the introduction and delivery for introduction into interstate commerce of such new drugs since there was no effective new drug application with respect to any of them.

DISPOSITION: On 10–16–61, a consent decree of permanent injunction was entered, enjoining the defendant from causing to be introduced or delivered for introduction into interstate commerce *Pre-Creatine capsules, Neo-Creatine capsules, Neo-Creatine granules, Vi-Arthra-M capsules* or any similar drug, or any other drug containing betaine anhydrous, glycocyamine, glycine, betaine, glucuronolactone, para-aminobenzoic acid, or sodium gentisate, without having an effective new drug application for such drug.

7002. Pre-Creatine capsules. (F.D.C. No. 45212. S. No. 23–401 R.)

INFORMATION FILED: 6–12–61, N. Dist. Calif., against Andrew Doty, t/a Creatine Laboratories, Inc., San Francisco, Calif.

SHIPPED: 1–19–60, from San Francisco, Calif., to Kansas City, Mo.

LABEL IN PART: (Btl.) "100 Capsules, PRE-CREATINE, Contains Precursors of Creatine Caution Federal Law Prohibits Dispensing without Prescription Manufactured for Creatine Laboratories, Inc., San Francisco."

CHARGE: 505(a)—when shipped, the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

PLEA: Guilty.

DISPOSITION: 11–6–61. $300 fine and probation for 2 years.

7003. Li-Bex with iron and succinylcholine chloride injection. (F.D.C. No. 47155. S. Nos. 23–357/8 T.)

QUANTITY: 357 vials, each in a plastic case, of *Li-Bex with iron* and 755 vials, each in a plastic case, of *succinylcholine chloride injection*, at Denver, Colo., in possession of Lyle A. Wittney & Co., Inc.

SHIPPED: Between 9–19–61 and 12–14–61, from Decatur and Chicago, Ill.